N27 W23910A Paul Rd
Pewaukee, WI 53072
Direct: (262) 347-1250
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NeoCoil

MAR 2 8 2013

5. Abbreviated 510(k) Summary

5.1. Applicant
NeoCoil, LLC
N27 W23910A Paul Rd
Pewaukee, WI 53072

5.2. Contact
Katie Gonzalez
Engineering Services Specialist
262-347-1250 (office)
261-347-1251 (fax)
katie.gonzalez@neocoil.com

5.3. Preparation Date
9/17/2012

5.4. Name of Device
- Proprietary Name: 1.5T 16ch Flex SPEEDER Coil
- Common Name: Magnetic Resonance Specialty Coil
- Classification: 21 CFR 892.1000, Product Code MOS

5.5. Model Numbers

NeoCoil Model Number	NeoCoil Model Name	Toshiba Model
NC043000	1.5T 16ch Flex SPEEDER Coil Large	MJAJ-227A/S1
NC042000	1.5T 16ch Flex SPEEDER Coil Medium	MJAJ-217A/S1

5.6. Device Description
The NeoCoil 1.5T 16ch Flex SPEEDER is a receive-only phased array coil system designed to provide high resolution imaging for the upper and lower extremities, chest, abdomen, pelvis, head, neck, and spine in pediatric and adult populations that can be interpreted by a trained physician. The system is compatible with 2D, 3D, parallel and isotropic imaging, as well as, coil signal intensity correction. The system consists of:
- Two formable, flexible and detachable antennae of different size that can be wrapped or orientated flat, in order to accommodate various anatomic shapes and sizes.
- Optional accessories designed for patient comfort and reduced motion artifacts.

The NeoCoil 1.5T 16ch Flex SPEEDER coil is tuned to receive RF frequency corresponding to the proton precession in a 1.5 tesla magnetic field, which is governed by the Larmor equation.

5.7. Predicate Device
- 1.5T 16ch Flex SPEEDER Coil (K121362), cleared on 06/15/2012

5.8. Comparison to Predicate
The NeoCoil 1.5T 16ch Flex SPEEDER coils are unchanged in physical, performance, design and material characteristics to the legally marketed device, the 1.5T 16ch Flex SPEEDER, K121362, as cleared on 06/15/2012.

The differences introduced in this submission include:
- Expanded Indications for Use with specific claims relating to pediatric populations.

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- Updated labeling that includes coil setup and positioning that support the expanded Indications for Use.

Use of the device in conjunction with an MRI scanner is unchanged; the specific claims in the expanded Indications for Use relating to pediatric populations have been added and are consistent with the capabilities of the 1.5T 16ch Flex SPEEDER Coil.

Clinical testing demonstrates that the differences in the devices do not affect the safety and/or the effectiveness of the device when used as labeled.

5.9. Indications for Use

To be used in conjunction with Toshiba 1.5T Magnetic Resonance Scanners with DL96 connectors to produce diagnostic images of the upper and lower extremities, chest, abdomen, pelvis, head, neck and spine in pediatric and adult populations that can be interpreted by a trained physician.

5.10. Intended Use

Intended use of the 1.5T 16ch Flex SPEEDER Coil is identical to that of routine MR imaging; specifically to produce diagnostic images of the upper and lower extremities, chest, abdomen, pelvis, head, neck, and spine.

5.11. Testing

The following data has been submitted, referenced or relied on to demonstrate that the 1.5T 16ch Flex SPEEDER Coil is safe and effective. The device's performance meets the requirements of pre-defined acceptance criteria and intended uses.

Performance testing - Bench:

Test	Pass/Fail Criteria	Result
Max B1 in first fault conditions	Pre-defined performance standards	**Pass:** Coil does not arc or show any signs of voltage breakdown. *No change from the legally marketed device, the 1.5T 16ch Flex SPEEDER, K121362, as cleared on 06/15/2012.
Surface Temperature in normal and first fault conditions	Pre-defined performance standards	**Pass:** RF heating is not greater than 39^{O} C in normal or first fault conditions.
NEMA MS 6-2008	Pre-defined performance standards	**Pass:** SNR and Uniformity are consistent with the requirements for the expanded Indications for Use. *No change from the legally marketed device, the 1.5T 16ch Flex SPEEDER, K121362, as cleared on 06/15/2012. Additional SNR and Uniformity measurements demonstrate acceptable performance when used with the Pediatric Stabilizer for head, neck and spine imaging.
Unplugged Surface Temperature	Acceptable level of risk	**Pass:** Surface temperature rise results in acceptable residual risk after mitigation.

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Published Standards testing:

The expanded Indications for Use introduced for the 1.5T 16ch Flex SPEEDER Coil in this submission have no impact to the results of standards testing of the predicate device, 1.5T 16ch Flex SPEEDER Coil, K121362, as cleared on 06/15/2012.

Additional standards testing were performed incorporating the added accessory, Pediatric SPEEDER accessory. Standards Data Report Forms (FDA 3654) are included in this submission, as applicable.

NOTE: Where indicated in the table below, new Standards testing was performed, as necessary, to support the expanded Indications for Use for pediatric populations. Standards testing that was not impacted by the introduction of the Pediatric SPEEDER accessory is listed as 'No change'.

Standard	Purpose	Comment
IEC 60601-1	Electromechanical safety	No change since K121362
IEC 60601-1-2	ESD	No change since K121362
IEC 60601-2-33	Electromechanical safety for magnetic resonance equipment	No change since K121362
ISO 10993-1	Biocompatibility	Additional risk assessment of Pediatric SPEEDER accessory performed.
NEMA MS6	Characterization of Special Purpose Coils for Diagnostic Magnetic Resonance Images	Characterization of 1.5T 16ch Flex SPEEDER Large and 1.5T 16ch Flex SPEEDER Medium in conjunction with the Pediatric SPEEDER accessory performed.

Performance testing - Clinical:
Clinical data submitted exhibits a mix of scanner configurations, pulse sequences, imaging options, field of view and anatomy in the axial, sagittal and coronal planes as recommended in the FDA guidance, *Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Diagnostic Devices*, issued November 14, 1998.

Clinical performance testing includes imaging from the pediatric subpopulations specified in Table 1 of the FDA guidance, *Premarket Assessment of Pediatric Medical Device* issued May 14, 2004.

No adverse events were reported during clinical performance testing; the 1.5T 16ch Flex SPEEDER Large and 1.5T 16ch Flex SPEEDER Medium coils demonstrated performance adequate to support the Indications for Use.

5.12. Conclusion

This submission demonstrates that the expanded Indications for Use associated with pediatric use are as safe and effective as the predicate device, 1.5T 16ch Flex SPEEDER coil, K121362, as cleared on 06/15/2012.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 28, 2013

NeoCoil, LLC
% Ms. Katie Gonzalez
Engineering Services Specialist
N27 W23910A Paul Road
PEWAUKEE WI 53072

Re: K123272
Trade/Device Name: 1.5T 16ch Flex SPEEDER Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: March 8, 2013
Received: March 13, 2013

Dear Ms. Gonzalez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123272

Device Name: 1.5T 16ch Flex SPEEDER

Indications for Use:

To be used in conjunction with Toshiba 1.5T Magnetic Resonance Scanners with DL96 connectors to produce diagnostic images of the upper and lower extremities, chest, abdomen, pelvis, head, neck and spine in pediatric and adult populations that can be interpreted by a trained physician.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) K123272